RECEIVED AT DRUG SAFETY SURVEILLANCE

12-JAN-1998-0542

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Novartis Pharmaceut
st Hanover, New Jersey
MANDATORY RE

Individual Safety Report
3034377-9-00

A. Patient information

1. Patient identifier: UNK (In confidence)
2. Age at time of event: 45 YR or Date of birth:
3. Sex: [ ] female [X] male
4. Weight: ____ lbs or ____ kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- [ ] death (mo/day/yr)
- [ ] life-threatening
- [ ] hospitalization - initial or prolonged
- [ ] disability
- [ ] congenital anomaly
- [ ] required intervention to prevent permanent impairment/damage
- [ ] other:

3. Date of Event (mo/day/yr): 05/1997

4. Date of this report (mo/day/yr): 06/11/1997

5. Describe event or problem

HEPATIC ENZYMES INCREASED
This patient who has a history of alcoholism and is HIV Positive was on Fioricet therapy in addition to other medications was found to have elevated liver function tests (no values available). Repeated liver function tests had shown improvement. The patient's physician believed the elevated liver function tests may be related to the patient's alcoholism as well as Fioricet administration. Fioricet was discontinued (date unknown).

6. Relevant tests/laboratory data, including dates

No laboratory information was provided

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

1) Alcoholism
2) HIV Positive
3) No known drug allergies

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Fioricet (butalbital, acetaminophen,
#2

2. Dose, frequency & route used
#1 Unspecified ORAL
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 Unspecified
#2

4. Diagnosis for use (indication)
#1 UNSPECIFIED
#2

5. Event abated after use stopped or dose reduced
#1 [ ] yes [ ] no [X] doesn't apply
#2 [ ] yes [ ] no [ ] doesn't apply

6. Lot # (if known)
#1 UNKNOWN
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 [ ] yes [ ] no [X] doesn't apply
#2 [ ] yes [ ] no [ ] doesn't apply

9. NDC # – for product problems only (if known)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)
1) Librium (chlordiazepoxide hydrochloride)
2) Mycelex troches (clotrimazole)
3) Crixivan (indinavir sulfate)
4) AZT (zidovudine)
5) amitriptyline

MORE

G. All manufacturers

1. Contact office – name/address (& mfring site for devices)
Novartis Pharmaceuticals Corp.
59 Route 10
East Hanover, NJ 07936-1080
USA

2. Phone number: 201-503-5530

3. Report source (check all that apply)
- [ ] foreign
- [ ] study
- [ ] literature
- [ ] consumer
- [X] health professional
- [ ] user facility
- [ ] company representative
- [ ] distributor
- [ ] other:

4. Date received by manufacturer (mo/day/yr): 06/11/1997

5. NDA# (A) 88-616
IND# ____
PLA # ____
pre-1938 [ ] yes
OTC product [ ] yes

6. If IND, protocol #

7. Type of report (check all that apply)
- [ ] 5-day [ ] 15-day
- [ ] 10-day [X] periodic
- [X] Initial [ ] follow-up #

8. Adverse event term(s)
HEPATIC ENZYMES INCREASED

9. Mfr. report number
USA/97/01496/FCT

E. Initial reporter

1. Name, address & phone #
[redacted] RPH
[redacted]

000010

2. Health professional? [X] yes [ ] no

3. Occupation: RPH

4. Initial reporter also sent report to FDA: [ ] yes [ ] no [X] unk

FDA

FDA Form 3500A facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Continued information

C1 Suspect Medication Name #1:
caffeine)

C10 Concomitant medical products:
6) Trazodone
7) Bactrim